

IN THE UNITED STATE DISTRICT COURT
FOR THE EASTERN DISTRICT OF NORTH CAROLINA
WESTERN DIVISION

GRAHAM YATES and BECKY YATES,)	
Plaintiffs,)	
)	
v.)	
)	Civil Action No. 5:12-cv-00752-FL
AIR & LIQUID SYSTEMS)	
CORPORATION, et al.,)	
Defendants.)	
)	

**FORD’S MEMORANDUM IN SUPPORT OF ITS *DAUBERT* MOTION
TO EXCLUDE THE TESTIMONY OF DR. MARK AND DR. BRODY**

Defendant Ford Motor Company (“Ford”) files this memorandum in support of its *Daubert* Motion to Exclude the Testimony of Dr. Mark and Dr. Brody and requests that Drs. Mark and Brody’s causation opinions be excluded for the following reasons.

INTRODUCTION

Plaintiffs designated Dr. Eugene Mark (a pathologist) and Dr. Arnold Brody (a cell biologist) to testify on the issue of general causation – i.e., whether exposure to chrysotile-containing, automotive products can cause mesothelioma. Dr. Mark was also designated to testify as to specific causation – i.e., whether Mr. Yates’ alleged exposure to Defendants’ chrysotile-containing, automotive products caused his mesothelioma.¹ However, Drs. Mark and Brody’s causation opinions fail to meet the reliability standards of Federal Rule of Evidence 702 and *Daubert*, and are irrelevant, unhelpful, prejudicial, and misleading to the jury for the following reasons. First, Drs. Mark and Brody’s theories that “each and every exposure” to asbestos contributed to Mr. Yates’ mesothelioma are entirely irrelevant and unhelpful

¹ Although wholly unqualified, Mr. Steve Hays (Plaintiffs’ industrial hygienist) has also offered causation opinions that Mr. Yates’ alleged exposures to asbestos from Defendants’ products exceeded background levels, and therefore caused Mr. Yates’ mesothelioma. To the extent Mr. Hays may attempt to offer such opinions at trial, such testimony should be precluded for the reasons set forth herein.

under the “substantial factor” test. Second, Drs. Mark and Brody admittedly have no facts or data to show that low level exposure from chrysotile-containing, automotive parts can cause mesothelioma and should not be permitted to speculate under the guise of expert testimony. In fact, Drs. Mark and Brody ignore the wealth of epidemiology studies – the “gold standard” of causation evidence – which show that brake work does *not* cause mesothelioma. Third, Dr. Mark’s opinions lack any identifiable methodology – as one court put it, Dr. Mark’s methodology is “merely an attempt to create an illusion of methodology which, in the end, lacked any substance that could be considered as generally accepted in the relevant scientific community.” *Nelson v. Am. Std.*, No. 081201335, 2008 WL 10718826 at *15 (Pa. Com. Pl. Sept. 24, 2008). Finally, Dr. Mark lacks sufficient information as to Mr. Yates’ alleged exposures to apply even his own, entirely arbitrary “methodology” to the facts of this case. For these reasons, Drs. Mark and Brody’s causation opinions have frequently been excluded by other courts² and should likewise be excluded in this case pursuant to Federal Rules of Evidence 403, 702, and *Daubert*.

BACKGROUND

I. Mr. Yates’ Alleged Asbestos Exposure.

Although Mr. Yates *never* worked as a mechanic, he alleges that he was exposed to brake dust containing chrysotile asbestos in the following ways:

² See *Kovary v. Honeywell Int., Inc.*, No. 10-494-GW-CW, Order at 6-7 (C.D. Cal. March 17, 2014) (excluding Dr. Mark’s testimony citing his “unhelpful tautology” and lack of a scientific methodology) (filed at D.E. 296-17); *Nelson*, 2008 WL 10718826 at *15 (rejecting Dr. Mark’s opinions because his “claimed methodology simply does not exist or is so convoluted and inherently contradictory so as to defy any comprehension”); *In re Asbestos Litig.*, No. 2004-03964, Order at 5-6 (Tex. 11th Dist. Ct. Jan. 20, 2004) (excluding Dr. Mark’s testimony that any exposure to any type of asbestos increases the risk of mesothelioma as unreliable because his theories are not “measurable” or “scientifically verifiable”) (filed at D.E. 296-22); *Krik v. Crane Co.*, No. 10-cv-7435, 2014 WL 7330901, *3-6 (N.D. Ill. Dec. 22, 2014) (excluding Dr. Brody’s “every exposure” opinion as unreliable because it lacks sufficient facts and data); *Sclafani v. Air and Liquid Sys. Corp.*, 2013 WL 2477077 at *4-5 (C.D. Cal. May 9, 2013) (rejecting Dr. Brody’s “every exposure” opinion because, as Dr. Brody conceded, “there was no data to establish that all exposures contribute to mesothelioma”) (filed at D.E. 296-7); *Borg-Warner Corp. v. Flores*, 232 S.W.3d 765, 773 (Tex. 2007) (same – excluding Dr. Brody); *Free v. Ametek*, No. 07-2-04091-9 SEA, Order at 3-4 (Sup. Ct. Wa. Feb. 29, 2008) (same – excluding Dr. Brody) (filed at D.E. 296-25).

A. Bendix.

1. As a bystander to mechanic work at two Esso gas stations between 1956 and 1957. *See* D.E. 296-2 at 70:4-16, 83:24-85:19. Mr. Yates' primary job duties were those of a gas station attendant and did not expose him to asbestos. *Id.* at 71:13-20. While Mr. Yates did not perform any maintenance work, he occasionally assisted the mechanics and swept the garage after brake work was performed.³ *Id.* at 71:21-77:1.
2. Opening new brake boxes while working as a parts clerk at the North Carolina Equipment Depot between 1961 and 1962. *Id.* at 79:8-85:19. Mr. Yates testified that he fetched replacement brakes and brought them to delivery truck drivers. His only alleged contact with brake dust was when he opened the boxes to confirm their contents. *Id.*
3. Two personal brake changes (on the front brakes only), in the 1950s and 1960. *Id.* at 19:19-21:25, 23:15-25:16.

B. Ford.

1. Two personal brake changes (on the front brakes only) in 1956 and 1958 using replacement brakes purchased from a Ford dealership. D.E. 175-1 at 149:4-152:22.
2. Opening new brake boxes, and occasional bystander exposure while visiting the mechanic areas, while working at an independent Ford dealership for less than three months in 1960. *See* Deposition of Dr. Mark at 340:7-341:8 (cumulative volumes attached hereto as **Exhibit A**); Mark Report at 5 (attached hereto as **Exhibit B**). Mr. Yates' duties at the Ford dealership were those of a parts clerk (pulling and stocking automotive parts) and a parts delivery driver (driving 300 miles a day delivering automotive parts). D.E. 175 at 171:3-172:21. Mr. Yates alleged that he was exposed to brake dust when he opened brake boxes containing new brakes to verify their contents and "on occasion" when he visited the mechanic areas of the dealership to observe or help the mechanics sweep the bays. D.E. 296-2 at 45:9-47:19, 51:24-54:9.

Throughout his pleadings in this action (and his bankruptcy trust Proof of Claim forms filed in other actions and in his claim for Veterans Administration benefits), Mr. Yates has alleged (and judicially admitted) that he was exposed to amosite asbestos when he served in the Navy from 1958 to 1960. *Id.* at

³Dr. Mark admits that approximately 99% of the chrysotile fibers found in brake linings are converted to a new compound called fosterite during the braking process and that fosterite does not cause mesothelioma. D.E. 296-5 at 1188:18-1189:2. Thus, to the extent Mr. Yates may be claiming exposure to "brake dust" from used brake linings during his personal brake changes or contained in mechanic areas where he visited, only 1% of that dust would be chrysotile asbestos fibers. Furthermore, to the extent those fibers were less than 5 microns, Dr. Mark admitted they would be too small to cause disease. *Id.* at 76:22-25.

34:5-37:22; D.E. 1; D.E. 346-3,4,5,6,7; Mark Dep. at 29:5-11. First, Mr. Yates was stationed as a seaman living onboard a YDT boat (which was used as an experimental torpedo station), where he visited crew members in the engine spaces “all the time.” D.E. 296-2 at 31:3-32:14. Next, he was stationed onboard the *U.S.S. Jonas Ingram* as a seaman and also visited crew members in the engineering spaces. *Id.* at 33:2-23. In 1960, Mr. Yates was transferred to the *U.S.S. Clarence K. Bronson*, a destroyer, where he was exposed to asbestos from thermally-insulated equipment—including boilers, pumps, pipes, motors and other equipment— while these products were being ripped out or maintained by others in “close proximity” to him, in “very tight space[s],” for periods of one hour to several hours every day for several months during the ship’s decommissioning. *Id.* at 34:5-37:22

II. Scientific Limitations In Determining The Cause Of Mesothelioma.

The following facts regarding causation of mesothelioma are well-known and are not contested in this action:

1. Exposure to asbestos is the most common cause of diffuse malignant mesothelioma. Mesothelioma may also be caused by exposure to erionite or radiation and some cases of mesothelioma are idiopathic (of unknown origin). Mark Dep. at 26:6-21.
2. Mesothelioma is a dose-responsive disease – in general, the greater the dose of asbestos, the greater the risk of developing mesothelioma. However, not all exposures to asbestos pose an equal risk of creating disease. *Id.* at 44:6-14.
3. The term “asbestos” refers to several different families of minerals – including the amphibole family (the most common forms of which include amosite, crocidolite, and tremolite) and the chrysotile family. Amphibole and chrysotile fibers vary significantly in their properties and potential toxicity. *Id.* at 33:25-39:13.
4. Amphiboles (most commonly amosite) are long, straight fibers which contain iron and are not easily soluble. D.E. 296-4 at 60:10-61:12; D.E. 296-5 at 1197:14-15. Due to their length and rigidity, amphiboles inhaled into the lungs are not easily removed by macrophages, one of the body’s clearance mechanisms to eliminate inhaled particles. Mark Dep. at 39:2-13. The half-life of amphiboles inside the human body is measured in years or decades. *Id.* at 38:14-16.
5. Chrysotile fibers, on the other hand, are wavy, serpentine fibers which are shorter in length and more soluble. D.E. 296-4 at 60:10-61:12. Due to their short length and tendency to break apart more easily, chrysotile fibers are more easily removed by the body’s

macrophages. Mark Dep. at 39:2-13; Deposition of Dr. Brody at 33:9-22 (attached hereto as **Exhibit C**). The half-life of chrysotile fibers inside the human body is measured in weeks or months. Mark Dep. at 38:11-13.

6. Automotive brakes were manufactured using chrysotile fibers which were subjected to intense heat and pressure (thereby “changing” the physical properties of the fibers) and then bound with resins. *Id.* at 41:13-44:5, 246:9-247:17; Brody Dep. at 90:3-91:24. Plaintiffs’ experts are unaware whether this manufacturing process alters the biological properties of the chrysotile fibers to render them inert and non-carcinogenic. *See id.* In any event, to the extent the chrysotile fibers remained bound with resin, they would not cause mesothelioma. Mark Dep. at 246:16-24. In addition, once brake linings are installed, during the braking process, approximately 99% of the chrysotile fibers found in brake linings are converted to a new compound called forsterite – which does not cause mesothelioma. D.E. 296-5 at 1188:18-1189:2.
7. Amphibole fibers are more potent and carcinogenic than chrysotile fibers. Mark Dep. at 61:10-14. If chrysotile fibers are able to cause mesothelioma, it would take a higher dose of chrysotile fibers to create the same risk of mesothelioma created by a low dose of amphibole fibers. *Id.* at 76:22-25; D.E. 296-5 at 1233:4-8.
8. Everyone has been exposed to chrysotile asbestos, which is ubiquitous in our air, drinking water, and thousands of consumer products. As a result, everyone has chrysotile asbestos fibers in their lungs. Mark Dep. at 78:5-79:9.
9. Scientists have not yet established the dose-response threshold under which exposure to chrysotile asbestos is not likely to cause mesothelioma. *See* Mark Report at 17; Brody Report at ¶¶44-45 (attached hereto as **Exhibit D**); Mark Dep. at 56:17-57:12.

This is where the areas of agreement end and the differences between concepts of regulatory prevention and legal causation begin.

Specifically, because science has not yet established the dose-response threshold under which exposure to chrysotile asbestos is not likely to cause mesothelioma, some government agencies,⁴ regulatory bodies, and plaintiffs’ experts (like Dr. Mark and Dr. Brody) have taken the position that “there is no known safe level of exposure” to any type of asbestos. While perhaps understandable as a

⁴ Conversely, OSHA has established the “permissible exposure limit” (“PEL”) for asbestos exposure which permits exposure up to .1 fiber/cc for an 8 hour time weighted average, and an “excursion limit” which permits exposures up to 1.0 fibers/cc over a 30 minute time frame.

prophylactic approach for risk prevention, this statement is not actually true and certainly does not suffice as a basis to attribute legal causation. Plaintiffs' experts inherently admit as much in their opinions that exposure to background levels of chrysotile asbestos in ambient air – which levels vary widely from city to city – does not increase the risk of mesothelioma. *See* D.E. 296-5 at 1217:12-1221:3; Brody Report at ¶¶44-45. Thus, it is not that a dose-response threshold for exposure to chrysotile asbestos does not exist, but that it has not been identified yet. Rather than acknowledging these scientific limitations, Drs. Mark and Brody attempt to transform the regulatory approach that “there is no safe level of exposure” into a causation theory that all asbestos exposures above background levels increase a person's risk of mesothelioma and therefore, cannot be eliminated from the causal chain if that person develops mesothelioma. *See* Brody Report at ¶¶44-45; Mark Dep. at 314:16-20.

As a preliminary matter, courts have repeatedly held that the findings of regulatory bodies are entirely irrelevant and incompetent to support opinions of legal causation. *See* n. 9 *infra*. More importantly, epidemiological evidence amassed over the last two decades definitively refutes the regulatory approach adopted by Drs. Mark and Brody and shows that exposure to chrysotile-containing automotive parts does **not** cause mesothelioma.

III. Drs. Mark and Brody Ignore Recent Epidemiology Studies Which Confirm That Brake Work Does *Not* Cause Mesothelioma.

Dr. David Garabrant, the only epidemiologist designated in this action, has submitted a detailed Affidavit describing twenty-one (21) epidemiological studies which have repeatedly confirmed that motor vehicle mechanics do **not** have an increased risk of mesothelioma. D.E. 296-3 at ¶18 (in sharp contrast to the career mechanics in these studies, however, Mr. Yates only alleges brief, occasional exposure to brake debris). Plaintiffs' experts, however, ignore these studies and rely instead on the lone study which arguably found a statistically significant association between mesothelioma and vehicle repair work – however, that study did not control for or exclude other asbestos exposures in the studied population and is, therefore, of limited value. *See* Mark Dep. at 324:5-328:13.

Likewise, Plaintiffs' experts also ignore a recent animal inhalation study which showed that chrysotile fibers inhaled from brake dust are quickly cleared from the lungs and do not cause damage to the lungs or pleura. Brody Dep. at 33:23–34:9; Mark Dep. at 249:5-19; Bernstein, D., et al, "Evaluation of the deposition, translocation and pathological response of brake dust with and without added chrysotile in comparison to crocidolite asbestos following short-term inhalation: Interim results," Toxicology and Applied Pharmacology, 276:28-46, 2014; Bernstein, DM, et al, "Evaluation of the fate and pathological response in the lung and pleura of brake dust alone and in combination with added chrysotile compared to crocidolite asbestos following short-term inhalation exposure," Toxicology and Applied Pharmacology 283:20-34, 2015. Instead, Dr. Mark relies on the outdated, select materials chosen for him by Plaintiffs' counsel. Science has progressed to firmly establish that exposure to chrysotile-containing automotive parts does *not* cause mesothelioma, but Plaintiffs' experts' opinions have remained the same.

IV. Drs. Mark And Brody's Speculative And Untested Causation Opinions.

Even if Drs. Mark and Brody were permitted to testify contrary to the overwhelming epidemiological evidence (which they should not), they still could not offer their "expert" opinions that Mr. Yates' alleged automotive exposures caused his disease because such opinions are based on untested, impermissible leaps of logic. More specifically, just because Drs. Mark and Brody cannot (or will not) "rule out" Mr. Yates' automotive exposures, they cannot "rule in" those exposures as "substantial factors" which caused his disease. Yet, that is exactly what they propose to do.

Specifically, Dr. Brody has articulated his partial, general causation opinion⁵ as follows:

Once a person develops an asbestos-related cancer, it is not possible to exclude any of the person's above-background level exposures to asbestos from the causal chain. Each and every exposure to asbestos that an individual with mesothelioma experienced in excess of a background level contributes to the development of the disease.

⁵ Dr. Brody only plans to opine that all exposures above background levels contribute to disease and Dr. Mark and Mr. Hays will testify that the exposures alleged by Mr. Yates exceeded background levels.

Brody Report at ¶44. This “each and every exposure” theory fails because it is based on admitted speculation (i.e., that exposures which cannot be excluded due to the lack of a dose-response threshold are nonetheless included) and because, to the extent it can be tested by comparison to epidemiological data, it has been proven false as applied to brake workers, who do *not* have an increased risk of mesothelioma.

Although Dr. Mark expresses his general causation opinion in different terms than Dr. Brody, closer inspection reveals that Dr. Mark’s theory is really his own “convoluted and inherently contradictory” version of the “each and every exposure” theory which cannot be defined, much less tested. *Nelson*, 2008 WL 10718826 at *14-15 (attached hereto as **Exhibit E**). In his own words, Dr. Mark opines that every “special exposure” (which he defines as “an exposure for which there is scientific reason to conclude that such an exposure creates a risk of developing the disease”) substantially contributes to the development of mesothelioma. Mark Dep. at 254:14-20. Although seemingly unable or unwilling to elaborate on his classification method for “special exposures” beyond his “unhelpful tautology,”⁶ Dr. Mark has previously confirmed that his category of “special exposures” includes all exposures above background levels because “there is scientific evidence that all the exposures in total cause mesothelioma.” D.E. 296-8 at 63:23-24; 137:13-138:16; *see also Nelson*, 2008 WL 10718826 at *14-15. To be sure, Dr. Mark spent two pages of his expert report comparing Mr. Yates’ alleged exposures to background levels in order to classify them as “special exposures.” *See Mark Report* at 5-7.

⁶ *Kovary*, No. 10-494-GW-CW, Order at 6-7 (describing Dr. Mark’s amorphous descriptions of his methodology as “unhelpful tautology”). Here, when asked to explain his classification method, Dr. Mark stated that he would need to organize his thoughts on the 20 different disciplines that he considers in reaching his opinions and that such an effort would take 30-45 minutes to articulate. *Id.* at 214:7-218:23; *see also id.* at 54:4-61:6, 299:6-300:11. When further asked which papers or treatises he relies upon from the philosophic discipline (one of his twenty disciplines), Dr. Mark was not able to identify any specific texts which could illuminate Defendants’ understanding of his theory (but nonetheless requested that a Greek translator be present to translate the original Greek texts by Plato, Sophocles, and Aristotle during his testimony at trial). *Id.* at 208:25-214:6.

Even more problematic than his “special exposures,” Dr. Mark has created another category of “trivial exposures” – which he defines as “exposure[s] for which there is no scientific reason to conclude that such an exposure creates risk of developing the disease” – which he excludes from his causation opinions. Mark Dep. at 254:14-20. Dr. Mark admits that there are no set criteria or “magical [dose] number” for what he deems a “trivial exposure.” *Id.* at 54:11-55:24. In fact, Dr. Mark has only been able to delineate the differences between “special” and “trivial” exposures by way of examples, which examples show that his classifications are entirely arbitrary and actually foreclose his opinions in this case:

■ Opening Brake Boxes – Although Dr. Mark classifies Mr. Yates’ alleged exposure in opening Ford brake boxes as a “special exposure” for purposes of this lawsuit, Dr. Mark previously testified that opening brake boxes would be a “trivial exposure.” *Id.* at 87:20-25. Apparently ignorant of the length of Mr. Yates’ alleged exposure, Dr. Mark attempted to explain this conflict by stating that opening brake boxes to count the number of brakes inside and taking the brakes out to look at them would be a “trivial exposure,” unless “you did it for *years* and saw visible dust.” *Id.* at 295:23-296:2; 340:13-341:6 (emphasis added). Here, Mr. Yates was allegedly exposed to Ford brake boxes for less than *three months*. *See id.* at 340:7-341:8.

■ One Day or 16 Hours of Exposure – Dr. Mark previously opined that it would take one day or 16 hours of exposure – to any type of asbestos – to classify an exposure as a “special exposure.” D.E. 296-8 at 62:9-20. Here, Dr. Mark opined that Mr. Yates’ alleged exposures from Ford products – opening brake boxes (which took only seconds), changing his own brakes on two occasions (front brakes only), and occasional bystander exposure to mechanic work (during his two-three months of employment at the Ford dealership) – were “special exposures” even though he lacks information that any of these alleged exposures (or even all of these exposures combined) exceeded 16 hours. Mark Dep. at 61:19-23, 81:22-82:22, 94:2-7, 141:8-21.⁷

In sum, Dr. Mark’s complete lack of objective criteria and consistency in assigning exposures to either his “special” or “trivial” categories renders his methodology and opinions “scientifically incoherent” and unreliable. *Nelson*, 2008 WL 10718826 at *37. Indeed, Dr. Mark’s equivocating,

⁷ Dr. Mark also previously opined that it would take at least one month of “*intense*” occupational exposure to asbestos to create a risk of mesothelioma (and therefore a “special exposure”). *Id.* at 91:15-24. Conversely, for purposes of this case, Dr. Mark opines that Mr. Yates’ *occasional bystander* exposure to brake dust in the mechanic areas of the Ford dealership during a two-three month period constitutes a “special exposure.” *See Mark Report* at 4-7.

unsupported testimony as to whether Mr. Yates' alleged exposures represent "trivial exposures" or "special exposures," reveal that his specific causation opinions are purely his own *ipse dixit* which cannot be tested and cannot survive scrutiny under Rule 702.

ARGUMENT

"The burden of laying the proper foundation for the admission of expert testimony is on the party offering the expert, and admissibility must be shown by a preponderance of the evidence." *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 592 n. 10 (1993). Federal Rule of Evidence 702 allows a Court to permit opinion testimony by a qualified expert only if:

- (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
- (b) the testimony is based on sufficient facts or data;
- (c) the testimony is the product of reliable principles and methods; and
- (d) the expert has reliably applied the principles and methods to the facts of the case.

Fed. R. Evid. 702. This Rule "assign[s] to the trial judge the task of ensuring that an expert's testimony both rests on a reliable foundation and is relevant to the task at hand." *Daubert*, 509 U.S. at 597. As explained below, Drs. Mark and Brody's opinions fail each of these standards.

I. Drs. Mark and Brody's "Each And Every" Opinions Are Not Helpful To The Jury Under The "Substantial Factor" Test.

Under North Carolina law, plaintiffs must demonstrate that Mr. Yates' alleged exposure to Ford's products was a "but for" cause of his mesothelioma – i.e., that his mesothelioma would not have occurred in absence of his alleged exposures to Ford products. *See McNair v. Boyette*, 282 N.C. 230, 236, 192 S.E.2d 457, 461 (1972). Although often expressed as the "substantial factor" test in cases with multiple alleged tortfeasors, North Carolina law is clear that Plaintiffs must prove that each Defendant's negligence "produced the result in continuous sequence, and without which it would not have occurred." *Id.*; *see also Prekler v. Owens-Corning Fiberglass Corp.*, 60 F.3d 824 (4th Cir. 1995) ("A defendant's conduct is a substantial factor when it 'has such an effect in producing the harm as to lead reasonable men to regard it as a cause' of the harm.")(quoting *Restatement (2nd) of Torts* § 431 cmt. a (1965));

Holmstrom v. C.R. England, Inc., 8 P.3d 281, 292 (Utah App. 2000) (“[No] case has been found where the defendant’s act could be called a substantial factor when the event would have occurred without it.”) (quoting W. Page Keeton, *Prosser and Keeton on the Law of Torts* § 41, 268 (5th ed. 1984)).⁸

Thus, in order for their opinions to be relevant and helpful to the jury, Drs. Mark and Brody must be able to opine that Mr. Yates’ alleged exposure to each Defendant’s products was a substantial factor in causing his injuries, without which his injuries would not have occurred. However, by its very terms, the “each and every exposure” theory is incompatible with the “*substantial* factor” test. Indeed, numerous courts have found that, if expert opinions that “there is no safe level of exposure to asbestos, and that every exposure to asbestos, however slight, was a substantial factor” in causing mesothelioma were sufficient for a plaintiff to meet his burden, the “‘substantial factor’ test would be meaningless.” *Lindstrom v. A-C Prod. Liab. Trust*, 424 F.3d 488, 493 (6th Cir. 2005); *Betz v. Pneumo Abex, LLC*, 44 A.3d 27, 56 (Pa. 2012) (holding that the “every exposure theory” is in “irreconcilable conflict with itself” and fundamentally inconsistent with the substantial factor test because if “each and every exposure” is a “substantial contributing cause,” then no exposure can be insubstantial); *Martin v. Cincinnati Gas & Elec. Co.*, 561 F.3d 439, 443 (6th Cir. 2009) (same); *Krik*, 2014 WL 7330901 at *3-6 (same); *Comardelle v. Pa. Gen. Ins.*, No. 13-6555, _F. Supp. _, 2015 WL 64279, *8 (E.D. La. Jan. 5, 2015) (same) (attached hereto as **Exhibit F**); *Davidson v. Ga. Pacific, LLC*, No. 12-1463, 2014 WL 3510268, *6 (W.D. La. July 14, 2014) (same) (attached hereto as **Exhibit G**); *Daly v. Arvinmeritor, Inc.*, No. 07-19211, Order at 7-8 (Fl. Cir. Ct. Nov. 30, 2009) (same) (filed at D.E. 296-19); *Free v. Ametek*, No. 07-2-04091-9 SEA, Order at 3-4 (Sup. Ct. Wa. Feb. 29, 2008) (same) (filed at D.E. 296-25); *Borg-Warner Corp. v. Flores*, 232

⁸ In assessing whether a plaintiff’s causation evidence is sufficient to get to the jury under the “substantial factor” test, the Fourth Circuit has adopted the “frequency, regularity, and proximity test” as a “standard for evaluating the sufficiency of the evidence of exposure” for motions as a matter of law. *Lohrmann v. Pittsburgh Corning Corp.*, 782 F.2d 1156, 1162 (4th Cir. 1986); *Jones v. Owens-Corning Fiberglass Corp.*, 69 F.3d 712, 716 (4th Cir. 1995) (applying North Carolina law). Although Plaintiffs’ forecast of evidence survived the *Lohrmann* summary judgment test (*see* D.E. 217), Plaintiffs have the burden of proving that each Defendant’s alleged negligence was a substantial factor and “but for” cause of their injuries at trial. *See Lohrmann*, 782 F.2d at 1162; *McNair*, 282 N.C. at 236.

S.W.3d 765, 773 (Tex. 2007) (same). Such a result is particularly appropriate here because Dr. Mark has testified that he cannot state that Mr. Yates' alleged exposures to brake dust increased his chances of developing mesothelioma by more than 1/1000% chance. *See* Mark Dep. at 99:9-25.

Furthermore, allowing causation experts to “rule in” exposures which cannot be ruled out would impermissibly shift the burden of proof to defendants – a dangerous precedent for asbestos and non-asbestos cases alike. *See Anderson v. Ford Motor Co.*, 950 F. Supp. 2d 1217, 1224 (D. Utah 2013) (“Just because we cannot rule anything out does not mean that we can rule everything in.”); *Smith v. Ford Motor Co.*, No 2:08-CV-630, 2013 WL 214378 at *3 (D. Utah Jan. 18, 2013) (rejecting expert opinions based on the “no safe level of exposure” theory because it “seeks to avoid not only the rules of evidence but more importantly the burden of proof.”) (filed at D.E. 296-23); *Sclafani v. Air and Liquid Sys. Corp.*, 2013 WL 2477077 at *4 (C.D. Cal. May 9, 2013) (same) (filed at D.E. 296-7).

II. Drs. Mark And Brody's Opinions Are Not Based On Sufficient Data.

It is a “fundamental tenet of toxicology that the dose makes the poison.” *Carroll v. Litton Sys., Inc.*, No. BC-88-253, 1990 WL 312969 at *28 (W.D.N.C. Oct. 29, 1990) *aff'd in part, rev'd in part* 47 F.3d 1164 (attached hereto as **Exhibit H**). Indeed, courts have routinely recognized that “all chemicals can cause health problems at some level or concentration of exposure, but they vary widely in the types of harm caused and in the levels of exposure required to trigger those harms. In addition, all chemicals have thresholds of exposure that must be exceeded before the harms will occur.” *Bombardiere v. Schumberger Tech. Corp.*, 934 F. Supp. 2d 843, 849 (N.D. W.Va. 2013); *Henricksen v. ConocoPhillips Co.*, 605 F. Supp. 2d 1142, 1161-62, 1165-66 (E.D. Wash. 2009) (collecting cases rejecting the “no threshold” theory as contrary to the fundamental tenet of toxicology that “the dose makes the poison”).

For that reason, causation experts in toxic tort cases must ascertain “the levels of exposure that are hazardous to human beings generally as well as the plaintiff's actual level of exposure” – without such information, expert testimony is neither reliable nor helpful to the jury. *Zellers v. NexTech Northeast, LLC*, 895 F. Supp. 2d 734, 739 (E.D. Va. 2012) (excluding expert testimony as irrelevant, unhelpful, and

unreliable because “[w]ithout reliable scientific knowledge of what level of exposure to R-404A is needed to produce [plaintiff’s disease], [plaintiff’s expert] can only speculate whether the level of [plaintiff’s] exposure to R-404A was significant enough to cause her condition.”); *see also Parker v. Mobil Oil Corp.*, 16 A.D.3d 648, 651 (Ny. App. 2005) (finding that the scientifically-reliable methodology for attributing causation requires experts to ascertain “the level of the toxin which will produce [the plaintiff’s] illness (i.e., the dose-response relationship)”) (filed at D.E. 296-6); *Mitchell v. Gencorp, Inc.*, 165 F.3d 778, 781 (10th Cir. 1999) (same); *Wright v. Williamette Ind., Inc.*, 91 F.3d 1105, 1107 (8th Cir. 1996) (same).

Unable to offer any evidence as to the dose-response threshold for chrysotile asbestos, Drs. Mark and Brody instead ask the Court to accept the premise that there *is* no threshold– i.e., that any exposure above background levels is sufficient to cause mesothelioma.⁹ Brody Report at ¶45; Mark Report at 17. As many courts have found, this “no threshold” theory is really an admission that the experts cannot meet their burden of showing the dose-response level necessary to cause disease. *See, e.g., Smith*, 2013 WL 214378 at *2 (“When [plaintiff’s expert] states that he cannot rule out any asbestos exposure as a possible cause of an individual’s mesothelioma he is confirming that there are insufficient facts and data to [support his expert opinion]”); *Butler v. Union Carbide Corp.*, No. 2008CA114, 2011 WL 2347505 at *11 (Ga. App. June 15, 2011) (same) (filed at D.E. 296-16); *Free*, No. 07-2-04091-9 SEA, Order at 3-4 (same). In fact, Dr. Mark conceded as much when he confirmed that he has “[no] underlying data on the

⁹ In attempt to validate this argument, Drs. Mark and Brody rely extensively on findings of regulatory bodies that “there is no safe level of exposure to asbestos.” Brody Report at ¶45 (citing the “conclusions of the IARC, WHO, NIOSH, CPSC and others”); Mark Report at 12, 17-22 (same). However, as set forth at length in D.E. 295 (which is incorporated herein by reference for the sake of brevity), courts have routinely found that the overriding preventative approach and lower causation standard of regulatory bodies renders their conclusions irrelevant and incompetent to support causation opinions in toxic tort cases. In addition to the authorities cited in D.E. 295, the court in *Juni v. A.O. Smith Water Prods.* recently excluded experts who relied upon regulatory bodies to support their “no safe level of exposure to asbestos” theory finding that “the reports and findings of governmental agencies are irrelevant as they constitute insufficient proof of causation.” _ N.Y.S.3d _, 2015 WL 1840006 at *29 (Ny. April 13, 2015) (collecting cases) (attached hereto as **Exhibit I**).

quantity of fibers found in brakes necessary to cause diffuse malignant mesothelioma in a human being.” Mark Dep. at 347:19-23.

In *Butler v. Union Carbide Corp.*, an asbestos plaintiff sought to introduce expert testimony based on the “no threshold” theory. See 2011 WL 2347505 at *9-12. The *Butler* court aptly found that “[t]he claim that there is no known safe level of exposure does not mean that none exists; it simply means that science today has not or cannot...determine what that level of exposure is.” *Id.* at 11-12. In rejecting the expert’s proffered testimony, the court explained that:

Daubert does not permit experts to speculate about what they concede is not known by use of the scientific method. The courtroom is not the place for scientific guesswork, even the inspired sort. *Law lags science; it does not lead it.*

Id. at 12 (emphasis in the original) (quoting *Rosa v. Ciba Geigy Corp.* 78 F.3d 316, 319 (7th Cir. 1996)). The *Butler* court further held that the “‘any exposure’ theory is, at most, **scientifically-grounded speculation: an untested and potentially untestable hypothesis.**” *Id.* at 15 (emphasis added); see also *Comardelle*, 2015 WL 64279 at *8 (“Although there may be no known safe level of asbestos exposure, this does not support [plaintiff’s expert’s] leap to the conclusion that therefore every exposure [plaintiff] had to asbestos must have been a substantial contributing cause of his mesothelioma.”); *Moore v. Ashland Chem., Inc.*, 151 F.3d 269, 278 (5th Cir. 1998) (excluding expert testimony because it “offered no scientific support for his general theory that exposure to toluene solution at any level would cause RADS”); *Anderson*, 950 F. Supp. 2d at 1224 (excluding plaintiffs’ causation experts because “their testimony is based on their lack of information sufficient to show the level of exposure which does not create a risk of mesothelioma”); *Smith*, 2013 WL 214378 at *2 (“Rule 702 and *Daubert* recognize above all else that to be useful to a jury an expert’s opinion must be based on sufficient facts and data. The every exposure theory is based on the opposite: a lack of facts and data.”).

Numerous courts have excluded Drs. Mark and Brody’s causation opinions for these very reasons. See *Kovary*, No. 10-494-GW-CW, Order at 6-7 (excluding Dr. Mark’s testimony because he lacked sufficient information to identify the dividing line between a safe and unsafe exposure); *Nelson*,

2008 WL 10718826 at *14-15, 37 (rejecting Dr. Mark’s “each and every exposure” opinions as “a maze of evidence [within which] no recognizable methodology was found”); *In re Asbestos Litig.*, No. 2004-03964, Order at 5-6 (Tex. 11th Dist. Ct. Jan. 20, 2004) (concluding that Dr. Mark’s testimony that any exposure to any type of asbestos increases the risk of mesothelioma is not “measurable” or “scientifically verifiable”); *Krik*, 2014 WL 7330901 at *3-6 (excluding Dr. Brody and several other experts who espoused the “every exposure” theory as lacking sufficient facts and data); *Sclafani*, 2013 WL 2477077 at *5 (rejecting Dr. Brody’s “every exposure” opinion because, as Dr. Brody conceded, “there was no data to establish that all exposures contribute to mesothelioma”); *Borg-Warner Corp.*, 232 S.W.3d 765, 773 (Tex. 2007) (same – excluding Dr. Brody); *Free*, No. 07-2-04091-9 SEA, Order at 3-4 (same – excluding Dr. Brody).

Accordingly, Drs. Mark and Brody’s opinions should be excluded because they are not based on sufficient data and, therefore are unreliable and unhelpful to the jury under Rule 702.

III. Dr. Mark’s Opinions Are Not The Product Of A Reliable Methodology.

Because Dr. Brody merely states a causation principle (which should be excluded for the reasons set forth above) and does not purport to apply any methodology, the following analysis refers only to Dr. Mark’s proffered testimony.¹⁰ Dr. Mark has repeatedly admitted that his conclusions are *not* based on scientific “theories” or “methodologies” – rather, he characterizes them as his “best evaluation.” Mark Dep. at 316:16-22, 343:4-344:12. The following analysis demonstrates that his undertaking (however it is termed) does not satisfy the reliability standards of Rule 702.

In assessing whether proffered expert testimony is the product of reliable principles and methods under Rule 702, courts are instructed to consider factors such as: (1) whether the testimony is “scientific knowledge” that derives from the scientific method; (2) whether it has been subjected to peer review and

¹⁰ However, to the extent the Court may find it appropriate to evaluate Dr. Brody’s opinion as a “method,” the portions of following analysis regarding the “each and every exposure” theory apply with equal force to Dr. Brody’s opinion.

publication; (3) whether the scientific technique has a high known or potential rate of error and whether there are standards controlling its operation; and (4) whether the theory or technique enjoys general acceptance within a relevant scientific community. *Daubert*, 509 U.S. at 592-93; *Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 203 (4th Cir. 2001). Here, Dr. Mark's opinions fail each of the above criteria.

A. Dr. Mark's Opinions Defy The Scientific Method.

Although Dr. Mark's report appropriately recites the scientific method, his analysis and conclusions ignore, and in fact defy, the following fundamental principles of the scientific method.

1. Dr. Mark's Opinions Are Based On Impermissible Assumptions And Downward Extrapolations.

Just as courts have rejected the "no threshold" theory as being based on "insufficient facts and data," courts have also rejected its "methodology" as lacking sufficient foundation. *See* Section II *supra*. More specifically, courts have held that the "no threshold" theory is really an impermissible "downward extrapolation" or assumption that, just because asbestos is known to be toxic at high doses of all fiber types, it must also be toxic in low doses of all fiber types.

For example, in *Free v. Ametek*, Drs. Brody and Hammar sought to testify that all asbestos exposures above background levels contribute to a person's mesothelioma, regardless of dose or fiber type. No. 07-2-04091-9 SEA, Order at 3-5 (filed at D.E. 296-25). The court found that those opinions are based on the assumption that the risk of mesothelioma at low levels of asbestos exposure "follows a straight line below the level of available data" for higher levels of exposure; however, such a downward extrapolation is "not proved by the empirical data." *Id.* at 4 (also rejecting reliance on regulatory analyses because the "regulatory standards are not probative of scientific analysis or acceptance in the scientific community"). Instead, relying on evidence presented by Dr. Garabrant, the court found that "the straight line correlation is not accurate for the data that are available, let alone for extrapolation to data that are not collected." *Id.* Accordingly, the *Free* court held that, while the "no safe level of exposure" theory may

be persuasive in “common sense” terms, it “is not supported by replicable, scientific methodology.” *Id.*; see also *Parker*, 16 A.D.3d at 652 (the “‘linear non-threshold model,’ assumes that ‘if a lot of something is bad for you, a little of the same thing, while perhaps not equally bad, must be so in some degree’...the scientific reliability of this methodology has flatly been rejected as *merely a hypothesis*”) (emphasis added); *Chikovsky v. Ortho Pharm. Corp.*, 832 F. Supp. 341, 345-46 (S.D. Fla. 1993) (rejecting an expert’s attempt to extrapolate from studies showing teratogenic effects of high doses of Vitamin A to low doses from Retin-A, which contains a derivative of Vitamin A).

Mirroring the facts in *Free*, Dr. Mark admits that he has “[no] underlying data on the quantity of fibers found in brakes necessary to cause diffuse malignant mesothelioma in a human being,” and that his “no threshold” opinions in this case are based on a downward extrapolation of data from higher exposures. Mark Dep. at 70:9-11, 347:19-23. Dr. Mark further admits that some carcinogens do not have a linear dose-response and that the scientific community does not know whether low-level asbestos exposures have a linear dose-response. *Id.* at 353:2-5. Here, as in *Free*, Dr. Garabrant has submitted evidence – which Plaintiffs have not and cannot refute – showing that low-level, chrysotile exposures among brake mechanics¹¹ do not cause mesothelioma. See D.E. 296-3 at ¶18-19. Thus, as in *Free*, Dr. Mark’s assumption that all low-level chrysotile exposures can be causative of mesothelioma is not only (admittedly) without empirical support, it is refuted by the empirical data. Accordingly, Dr. Mark’s opinions should be rejected as unfounded and unreliable.

2. Dr. Mark’s Opinions Impermissibly Substitute The Disease For The Methodology.

Dr. Mark’s opinions rest on the circular, unscientific reasoning that the presence of the disease is sufficient to prove its cause – in his words, “the disease is the methodology.” D.E. 296-8 at 22:24. In fact, Dr. Mark’s report claims that “[t]he causation link between asbestos exposure and diffuse malignant mesothelioma is so well established that when diffuse malignant mesothelioma occurs it ‘signals’ prior

¹¹ Mr. Yates never worked as brake mechanic and only alleges occasional exposure to brake dust – a minute fraction of that received by the career mechanics included within the epidemiological studies.

asbestos exposure even when the victim cannot recall the exposure which may have occurred many years previously and have been invisible or unappreciated at the time.” Mark Report at 10. This presumptuous approach fails to account for the occurrence of idiopathic cases of mesothelioma and makes leaps of logic which are unsupported by scientific evidence. *See Butler*, 2011 WL 2347505 at *11 (“It is improper for an expert to presume that the plaintiff must have somehow been exposed to a high enough dose to exceed the threshold necessary to cause the illness, thereby justifying his initial diagnosis. *This is circular reasoning.*”) (emphasis in the original) (quoting *Mancuso v. Consol. Edison Co. of Ny.*, 967 F. Supp. 1437, 1450 (S.D.N.Y. 1997)). Accordingly, Dr. Mark’s statement that “the disease is the methodology” is inherently an admission as to his lack of methodology. *See id.*; *In re Agent Orange Prod. Liab. Litig.*, 373 F. Supp. 2d 7, 32 (E.D.N.Y. 2005) (“The fact that diseases were experienced by some people after spraying does not suffice to prove general or specific causation, i.e., that the harm resulted to individuals *because* of the spraying. *Post hoc ergo propter hoc* remains a logical fallacy unacceptable in toxic tort law.”).

Moreover, even if Dr. Mark’s assumption that mesothelioma is always a “signal tumor for asbestos exposure” were correct, the presence of a “signal tumor” in no way signals which asbestos exposure caused it. Indeed, Dr. Mark admits that chrysotile fibers less than 5 microns in length are not carcinogenic, that he does not know whether chrysotile fibers in brake linings are rendered biologically inert during the manufacturing process, and that all chrysotile fibers are less potent and less carcinogenic than the amphibole-containing products to which Mr. Yates was exposed in the Navy. Mark Dep. at 29:5-11, 41:13-44:5, 61:10-14, 76:22-25. Dr. Mark further admits that the short chrysotile fibers are cleared from the body within weeks to months while the longer, amphibole fibers may remain in the body for decades. *Id.* at 39:2-13. These admissions are in irreconcilable conflict with his opinion that both chrysotile and amphibole exposures become carcinogenic at the same dose (any amount above

background)¹² and substantially contribute to disease in the same manner. D.E. 296-4 at 61:23-63:10, 77:14-78:5. For these reasons, courts have frequently excluded expert opinions, including those of Dr. Mark, which fail to account for dose or fiber type. See *Comardelle*, 2015 WL 64279 at *8 (excluding expert opinion based on the every exposure theory because it “elides any differences or nuances of duration, concentration, exposure, and the properties of the fibers to which [plaintiff] may have been exposed”); *In re Asbestos Litig.*, No. 2004-03964, Order at 5 (in light of Dr. Mark’s admissions “that chrysotile asbestos (the kind found in friction products) was much less likely to cause asbestos disease” than amosite, the court concluded that the extent to which “any exposure” causes disease “is not measureable nor is it scientifically verifiable.”); *Anderson*, 950 F. Supp. 2d at 1223 (“Just because we cannot rule anything out does not mean that we can rule everything in.”); *Betz*, 44 A.3d at 56 (finding that the “any-exposure opinion is in irreconcilable conflict with itself” because it fails to account for the different fiber potencies and “one cannot simultaneously maintain that a single fiber among millions is substantially causative, while also conceding that a disease is dose responsive”); *Smith*, 2013 WL 214378 at *2 (expert opinion that all exposures play a contributing role based on the “no threshold” theory “asks too much from too little evidence as far as the law is concerned”).

In sum, Dr. Mark’s opinion that all exposures – to any type of asbestos at any dose above background – contribute to disease at the same level cannot stand in the face of his admissions that it would take a higher dose of chrysotile than amphibole asbestos to cause mesothelioma. D.E. 296-5 at 1233:4-8.

¹² If the dose-response threshold for exposure to amphibole asbestos was truly background level, then the threshold for exposure to chrysotile asbestos would have to be some number higher. This begs the question of which city’s background level should be used? Since background levels vary significantly, yet no city’s background level is claimed to pose a risk of mesothelioma, presumably the highest background level would apply. Query also why background level was chosen as a surrogate threshold for all types of asbestos under the “no threshold” theory when most, if not all, “background” asbestos in the U.S. is chrysotile, not amphibole? These considerations confirm that “background level” is a purely arbitrary comparison and an unscientific attempt to compensate for the lack of a dose-response threshold.

3. Dr. Mark's Opinions Ignore, And Impermissibly Conflict With, Definitive Epidemiological Evidence.

Dr. Mark agrees that epidemiological evidence is important in determining whether exposure to brake dust is capable of causing mesothelioma. Mark Dep. at 69:20-70:2. Dr. Brody describes epidemiological evidence as the “gold standard” of causation evidence in toxic tort cases and the “best tool to determine whether exposure to asbestos containing brakes or products creates an increased risk.” D.E. 296-26 at 140:10-25; *see also* D.E. 296-3 at ¶21 (“A failure to consider the relevant epidemiological evidence is neither a reliable method for reaching conclusions nor is it an accepted method in the scientific community.”); *Norris v. Baxter Healthcare Corp.*, 397 F.3d 878, 882 (10th Cir. 2005) (“epidemiology is the best evidence of general causation in a toxic tort case”); *Siharath v. Sandoz Pharm. Corp.*, 131 F. Supp. 2d 1347, 1358 (N.D. Ga. 2001) (“The absence of epidemiological support raises the question of whether the causation opinions of Plaintiffs’ experts are merely speculative and not based on scientific knowledge.”).

Here, twenty-one epidemiological studies have definitively and repeatedly established that brake mechanics do **not** have an increased risk of mesothelioma. D.E. 296-3 at ¶18-19. In a pained attempt to justify his rejection of those studies, Dr. Mark claims that he relies instead on the Australian Mesothelioma Registry (the “AMR”), which he describes as “the largest” epidemiological study and which he claims found an increased risk of mesothelioma for brake mechanics. Mark Dep. at 334:3-335:13. First, Dr. Mark’s classification of the AMR as an epidemiological study is incorrect – as Dr. Mark acknowledges, the AMR’s principal researcher has confirmed under oath that the AMR is **not** an epidemiological study. *See id.*; *see also* D.E. 276 (describing a host of other problems which render the AMR irrelevant and unreliable). Moreover, Dr. Mark admits that the AMR did not control for or exclude other asbestos exposures of the studied population (including mining and residential exposures which were common in Australia where amphibole asbestos was mined and used in residential construction products) –thereby rendering its findings irrelevant and unreliable, especially in comparison to the

twenty-one controlled studies which have repeatedly found no increased risk of mesothelioma in brake workers. *Id.* at 354:20-357:22.¹³ Thus, not only has Dr. Mark failed to identify a single, reliable epidemiological study which supports his opinions, he inexplicably ignores the twenty-one epidemiological studies which foreclose his opinions.

Courts have frequently rejected causation opinions, like those of Dr. Mark, which run afoul of established epidemiological evidence as inherently unreliable. *See Norris*, 397 F.3d at 882 (holding that epidemiological studies are not required to prove causation, but that a substantial body of epidemiological evidence challenging causation cannot be ignored); *Allison v. McGhon Med. Corp.*, 184 F.3d 1300, 1316 (11th Cir. 1999) (animal studies and case reports were properly excluded in the face of overwhelming contrary epidemiological evidence); *Richardson v Richardson-Merrell, Inc.*, 857 F.2d 823, 830-31 (D.C. Cir. 1988) (affirming judgment as a matter of law where plaintiff's experts could not rebut epidemiological evidence that the product did not cause the plaintiff's alleged injuries – “the law now has the benefit of twenty years of scientific study, and the published results must be given their just due”); *Juni*, 2015 WL 1840006 at *29 (rejecting expert testimony that exposure to automotive friction products caused plaintiffs' mesothelioma because plaintiffs' expert failed to rebut the wealth of epidemiological evidence to the contrary); *Smith*, 2013 WL 214378 at *2 (“Separate and apart from the lack of any reliable scientific methodology or data that supports [the expert's] opinion, the research that has been done contradicts his point of view.”)

¹³ At other times, Dr. Mark has cited the study authored by Roelofs *et al*, the lone epidemiological study which arguably found a statistically significant incidence of mesothelioma in brake mechanics. Mark Dep. at 320:6-16, 324:5-328:22. However, like the AMR, Dr. Mark concedes that the Roelofs study carries a limiting provision cautioning that it captures only the subjects' usual occupations and does not control for or exclude their other asbestos exposures – again rendering its findings irrelevant and unreliable. *See id.*; D.E. 296-3 at ¶18. Furthermore, Mr. Yates never worked as a brake mechanic and only alleges a slight fraction of the exposures received by the studied population of career mechanics.

4. Dr. Mark Does Not Use a Reliable Methodology to Identify the Level of Exposure to Ford Brake Dust Necessary to Cause Mesothelioma.

Ford's product, for purposes of this case, is the brake dust that Mr. Yates claims he was exposed to from opening brake boxes containing new brakes and from visiting the mechanic areas of the dealership "on occasion" to observe or to help the mechanics sweep the bays. It is true, of course, that Ford brake pads distributed during the period when Mr. Yates claims exposure contained chrysotile asbestos. Based on this fact, Dr. Mark assumes - tacitly and explicitly - that brake dust and chrysotile asbestos are effectively identical substances in terms of their respective capacities to cause mesothelioma. Experts, however, are not permitted to blithely assume that one substance is equivalent to another. Further, Dr. Mark's assumption flies in the face of (1) the overwhelming epidemiological evidence distinguishing the two substances and (2) his own testimony regarding the potential impact of the brake manufacturing process on chrysotile asbestos.

The applicable scientific literature establishes that brake dust contains little, if any, chrysotile asbestos and what chrysotile asbestos remains has been modified by the heat and pressure of both the braking process and the brake pad manufacturing process:

Studies have shown that thermal treatment and mechanical manipulation of chrysotile alters both its surface and structure. Service conditions created on brake pads both heats and tears down the fiber. Chrysotile subjected to these severe conditions cannot, and does not, retain its natural properties. Chrysotile biological activity is thereby greatly reduced, and can become virtually nil hundreds of degrees below the olivine transformation temperature. Complete transformation of the mineral is not required to result in loss of activity. Exposure to brake wear debris, which has been created as the result of these forces, may be associated with little or no risk of asbestos disease. Blowouts and cleanups of wear debris, both visually dusty work practices, might constitute no asbestos hazard to workers.

(Langer, AM. *Reduction of the biological potential of chrysotile asbestos arising from conditions of service on brake pads*. Regulatory Toxicology and Pharmacology (2003) 38:71-77 at 76, attached hereto as **Exhibit J**; see also Fisher, GL, Mossman, BT, McFarland, AR, Hart, RW. *A Possible Mechanism of Chrysotile Asbestos Toxicity*. Drug and Chemical Toxicology (1987) 10(1&2)109-131 at 110, 111 ("The

results, in a number of different cell types and bioassays with different endpoints, show that biological effects of chrysotile can be diminished by heating[.]” attached hereto as **Exhibit K**; Fubini, B. *Surface Reactivity in the Pathogenic Response to Particulates*. Environmental Health Perspectives (1997) 105 (Suppl 5)1013-1020 at 1014 (“[P]rolonged grinding deeply modifies and inactivates chrysotile asbestos.”).) attached hereto as **Exhibit L**. Indeed, as Dr. Mark has previously admitted, most of the chrysotile asbestos in brakes is converted to biologically-inert forsterite by the heat and pressure of the braking process.

Furthermore, the chrysotile asbestos found in brake pads may have been inactivated long before the braking process even began. The manufacturing process used to create brake pads involves applying significant heat and pressure to the chrysotile asbestos forming part of their composition. In addition to being repeatedly heated (on at least one occasion to 400 degrees Fahrenheit for five hours), the asbestos in the brake pads was subjected to pressures of approximately 1800 PSI and soaked in naphtha. These sorts of manipulations have been shown to “inactivate” chrysotile fibers, greatly reducing or eliminating their potential to cause cancer. (See Langer, *supra*, at 71, 76; Valentine, R, et al. *Thermal Modification of Chrysotile Asbestos: Evidence for Decreased Cytotoxicity*, Environmental Health Perspectives (1983) 51:357-368 at 363.) attached hereto as **Exhibit M**.

Dr. Mark admitted that he was aware of the heat and pressure involved in the brake manufacturing process but also admitted that he was unfamiliar with the Langer paper. In other words, despite basing his causation opinion on the amount of brake dust exposure necessary to cause mesothelioma and the fact that brake pads contain chrysotile asbestos, Dr. Mark chose not to investigate the effect of heat and pressure on that chrysotile asbestos. When asked specifically about the Langer paper and its conclusions, Dr. Mark professed little knowledge:

Q. Let me hand you, sir, what's been marked as Exhibit 9, and this is an article by Langer which is entitled "Reduction of the biological potential of chrysotile asbestos arising from conditions of service on brake pads" published in 2002. First, sir, did you previously review and consider this article in reaching your opinions?

A. (Witness reviews document) I don't remember that I've seen this -- this specific article before. I might have. I don't know.

Q. If I could ask you to turn to Page 76, sir, and I'd like to read some statements to you and ask you if you agree with them or whether you formed an opinion on that point. Looking specifically at Page 76 under Conclusions, it states, quote, Studies have shown that thermal treatment and mechanical manipulation of chrysotile alters both its surface and structure. Service conditions created on brake pads both heats and tears down the fiber. Chrysotile subjected to these severe conditions cannot and does not retain its natural properties. Chrysotile biological activity is thereby greatly reduced and can become virtually nil hundreds of degrees before the olivine transformation temperature. Complete transformation of the mineral is not required to result in loss of activity, end quote. First, sir, did I read that correctly?

A. Yes.

Q. Alright. And let me go through it and parse it out now. Would you agree with me that studies have shown that thermal treatment and mechanical manipulation of chrysotile alters both its surface and structure?

A. Now, since I haven't seen this study before, give me a moment to read the abstract to put that discussion paragraph into context.

Q. Certainly, sir. Take all of the time you need.

A. (Witness reviews document) Now, would you please read back the question or ask it again.

Q. I can -- I can ask it again. First, let me -- I'm going to ask a different question first, sir. Doctor, you've now had a few minutes to take a look at the Langer article, correct?

A. Yes.

Q. Alright. And, looking at the statement on Page 76, sir, would you agree that studies have shown that thermal treatment and mechanical manipulation of chrysotile alters both its surface and structure?

A. Yes.

Q. Would you agree that surface conditions created on brake pads both heat and tear down the fiber?

A. Both heats and tears down the fiber, yes.

Q. Would you agree that chrysotile subjected to these severe conditions cannot and does not retain its natural properties?

A. No. I wouldn't agree with that entirely.

Q. Okay. You said not entirely, sir. Is there a portion of that statement you would agree with?

A. I would say that chrysotile subjected to these severe conditions in part does not retain natural properties but in part might depending on the heat and time.

Q. Okay. Would you agree that chrysotile biological activity is greatly reduced and can become virtually nil hundreds of degrees below the olivine transformation temperature?

A. I don't know.

Mark Dep. at 40:23-43:19.

The object disregard for the salient issue of whether the pathogenic potential of brake dust is, in fact, substantially similar to that of chrysotile asbestos demonstrates the lack of reliability in the methodology of Dr. Mark. Dr. Mark's assumption that brake dust and chrysotile asbestos are pathogenically similar has not been tested or peer-reviewed, and the theory is far from generally accepted in the relevant field. To the contrary, as discussed above, the vast bulk of medical and scientific literature contradicts the causation theory of Dr. Mark in this case. *See Norris v. Baxter Healthcare Corp.*, 397 F.3d 878, 884-886 (10th Cir. 2005) (excluding expert causation opinion because it contradicted the available epidemiological evidence).

B. Dr. Mark's Opinions Have Not Been Subjected To Peer Review, Cannot Be Tested, And Carry A Significant Potential Error Rate.

In order for a theory to be subject to peer review or evaluated based on its rate of error, it must first be testable – and if a theory cannot be tested, it cannot “achieve the designation of ‘science.’” *See Butler*, 2011 WL 2347505 at *9 (quotations omitted); *United States v. Bynum*, 3 F.3d 769, 773 (4th Cir. 1993) (“‘Scientific’ knowledge is generated through the scientific method-submitting testable hypotheses to the crucible of experiment in an effort to disprove them. An opinion that defies testing, however defensible or deeply held, is not scientific.”).

Here, Dr. Mark's method of classifying exposures as "special exposures" or "trivial exposures" cannot qualify as "scientific under these standards because it has not even been committed to writing or expressed in words beyond his basic definitions stated above. Mark Dep. at 48:21-49:13. In fact, when asked "[h]ow would someone, other than you, interpret how you're defining special exposures, other than looking at a dictionary," Dr. Mark replied as follows:

I would think that one would start with having some basic science in college, having four years of medical school, doing a pathology residency or some other medical residency, and then having years of experience in deciding on the various forms of asbestos, the various methods by which people are exposed, the various movements by which – by which asbestos fibers work through the body, the various cytological mechanisms which could ensue, as we discussed yesterday, epidemiology included, work practice studies, understanding the literature including governmental agencies, understanding more basic physics and mineralogy about asbestos, what it is and what it can do and where it's located and how it's used, understanding the historical basis by which we came to understand why asbestos is a problem in our society. And, if a person didn't have some knowledge of those facets, then it might be hard, and I think it would be optimal if a person did understand the full breadth of asbestos mineralogy, asbestos physics, asbestos chemistry, asbestos biology, because if you are going to make a sweeping conclusion or a non-sweeping conclusion, any conclusion, it's best to have a broad understanding of asbestos and its various aspects.

Id. at 299:11-300:11. In essence, only a learned expert (and perhaps only Dr. Mark) will "know it when they see it." For this very reason, the *Kovary* court rejected Dr. Mark's causation opinions citing his "unhelpful tautology" and inability to explain his methods. D.E. 296-17 at 6. Similarly, the *Nelson* court rejected Dr. Mark's methods as "merely an attempt to create an illusion of methodology." 2008 WL 10718826 at *15.

Thus, because Dr. Mark's methodology cannot be defined, much less replicated, it cannot be tested to determine its error rate. Dr. Mark has explicitly confirmed that his opinions cannot be tested because "you cannot test concepts." *Id.* at 214:7-23. Even if the results of Dr. Mark's "concepts" of "special exposures" in this case were tested by comparison to his "concepts" of "trivial exposures," such a comparison reveals that his method has a 100% error rate in this case. *See p. 9 infra*. Specifically, Dr. Mark's testimony that opening brake boxes is a "trivial exposure" unless performed repetitively for

“years” irreconcilably conflicts with his opinion that Mr. Yates’ alleged exposure in opening Ford brake boxes for two-three months is a “special exposure.” Similarly, Dr. Mark’s testimony that 16 hours of exposure is the minimum duration necessary to create a risk of mesothelioma irreconcilably conflicts with his opinion that Mr. Yates’ alleged exposure to Ford brake dust on the few random occasions he visited the mechanic areas of the Ford dealership and the two occasions on which he allegedly replaced his front brakes using Ford replacement parts were “special exposures” even though he cannot say that their combined duration exceeded 16 hours. *See* Mark Dep. at 81:22-82:22, 94:2-7, 141:8-21.

These discrepancies reveal that Dr. Mark’s opinions are nothing more than the *ipse dixit* of a professional witness which do not satisfy the reliability standards of Rule 702 or *Daubert*. *See Gen. Elec. Co. v Joiner*, 522 U.S. 136, 146 (1997) (district courts should not “admit opinion evidence which is connected to existing data only by the *ipse dixit* of the expert”).

C. Dr. Mark’s “Theory” Is Not A Generally Accepted Methodology.

Dr. Mark’s theory or technique of dividing asbestos exposures between “special exposures” and “trivial exposures” is his own invention which has not been peer-reviewed and cannot be tested, and therefore, can never attain “general acceptance” in the scientific community. *See* D.E. 296-9 at 40:14-41:1 (stating that his “special exposure” and “trivial exposure” terms are defined only in the dictionary and are not found in any scientific or peer-reviewed literature). As described by the *Nelson* court, Dr. Mark’s technique is “an attempt to create an illusion of methodology which, in the end, lacked any substance that could be considered as generally accepted in the relevant scientific community.” *Nelson*, 2008 WL 10718826 at *15.

To the extent Dr. Mark’s theory may be evaluated based on his underlying premise that “there is scientific evidence that all the exposures in total cause mesothelioma” (*see* D.E. 296-8 at 59:23-24), Dr. Mark relies heavily on the list of governmental agencies and regulatory bodies which have accepted the mantra that there is no safe level of exposure to asbestos. Mark Report at 17-21. However, courts have regularly held that “the reports and findings of governmental agencies are irrelevant as they constitute

insufficient proof of causation” and cannot be used to support the admission of causation opinions in civil cases. *See, e.g., Juni*, 2015 WL 1840006 at *29; *see also* D.E. 295 (which is incorporated by reference herein); *Richardson*, 857 F.2d at 830-31 (“Since the [plaintiffs] had the burden of proving that Bendectin causes birth defects, the law cannot tolerate a presumption of teratogenicity. That may be prudent in the medical community at the early stages of research where caution is vital and suspicion comes naturally, but it obviously is not acceptable when teratogenicity becomes an issue in a judicial tribunal.”).

Particularly in recent years since epidemiological evidence has proven Dr. Mark’s opinions and the preventative approach of regulatory bodies to be a gross overgeneralization and demonstrably false in the context of low-dose chrysotile exposures experienced by brake mechanics, an increasing number of courts across the nation have found that opinions based on the “no threshold” or “each and every exposure above background levels” theories are unreliable and inadmissible in asbestos cases. *See* Cases Excluding the “Each and Every Exposure” Theory attached hereto as **Exhibit N**.

Accordingly, Dr. Mark’s general causation opinions should be excluded because they are not based on reliable methodology.

IV. Dr. Mark’s Specific Causation Opinions Do Not Apply Reliable Methods To The Facts Of This Case.

In order to be relevant and helpful to the jury, Dr. Mark’s specific causation opinions must “demonstrate[e] the probability that the toxin caused the particular plaintiff’s illness, which involves weighing the possibility of other causes of the illness.” *Parker*, 16 A.D.3d at 651; *In re Agent Orange Prod. Liab. Litig.*, 611 F. Supp. at 1250 (to prove specific causation, plaintiffs’ expert must first prove general causation and then exclude other possible causes for the plaintiff’s injury).

While Dr. Mark’s report states that Defendants’ products were a “medical cause” of Mr. Yates’ mesothelioma, his testimony reveals that opinion to be pure speculation. First, Dr. Mark admittedly lacks sufficient information as to the dose-response threshold necessary to cause disease generally. *See* Section II *supra*. Second, Dr. Mark lacks sufficient information as to the duration and doses of Mr. Yates’ alleged

exposures to Defendants' products to reach the conclusion that those exposures qualify as "special exposures" (even under his own theory). Specifically, Dr. Mark conceded that he has not calculated the duration of Mr. Yates' alleged exposures –which information would be necessary in order to ascertain the cumulative dose – and cannot say that Mr. Yates' cumulative exposure to asbestos from Defendants' products (combined) exceeded .1 fibers/cc/years.¹⁴ Mark Dep. at 94:2-7, 141:8-12. Accordingly, Dr. Mark cannot even compare the cumulative dose allegedly received by Mr. Yates from Defendants' products to the cumulative doses received from background levels. Mark Dep. at 61:19-23, 141:8-21.

Furthermore, Dr. Mark has made no effort to rule out Mr. Yates' Naval exposures to amosite asbestos – which Dr. Mark admits to be more potent and carcinogenic than chrysotile asbestos. Mark Dep. at 29:5-11, 98:14-18, 1233:4-8. This failure, standing alone, presents sufficient reason to reject Dr. Mark's opinions as unreliable. *See Cooper*, 259 F.3d at 202 (“[I]f an expert utterly fails to consider alternative causes or offer an explanation for why the proffered alternative cause was not the sole cause, a district court is justified in excluding the expert’s testimony.”); *Zellers*, 895 F. Supp. 2d at 742 (E.D. Va. 2012) (same); Fed. R. Evid. 702, Adv. Cmte Note (2000 Amendment) (courts may consider whether an expert has adequately accounted for alternative explanations in deciding whether the expert’s opinion is reliable).

Finally, Dr. Mark's arbitrary and conflicting classifications of exposures as "trivial" leaves no question that his specific causation opinions do not satisfy the reliability standards of Rule 702. Dr. Mark cannot in one instance include the exposures described by Mr. Yates within those he classifies as "trivial,"

¹⁴ Dr. Mark's report provides estimated peak or excursion levels of exposure that Mr. Yates *may* have received in his various tasks as compared to an assumed background level of 0.00005 fibers/cc, but this comparison is meaningless without the essential element of time. For instance, for a person living in San Francisco for 70 years, the cumulative dose of asbestos received from background/ambient air would be 2.5 fibers/cc/years. *See* Trial Testimony of Dr. James Crapo at 2539:3-7, attached hereto as **Exhibit O**. Without calculating the duration of Mr. Yates' alleged exposures, Dr. Mark cannot estimate Mr. Yates' cumulative dose from Defendants' products and therefore, cannot draw the conclusion that those exposures exceeded the cumulative background levels of asbestos.

yet expect to testify before this jury that they were “a substantial contributing factor and medical cause” of Mr. Yates’ mesothelioma. Rather, Dr. Mark’s conflicting testimony in attempt to meet the needs of this case supports the *Nelson* court’s assessment that Dr. Mark “comes to the ‘right’ conclusion first and then decides which ‘methodology’ will support the conclusion.” 2008 WL 10718826 at *15.

In sum, Dr. Mark has not applied reliable methods to the facts of this case as required by Rule 702 and his specific causation opinions are entirely unhelpful, prejudicial, and misleading to the jury.

CONCLUSION

For the foregoing reasons, Dr. Mark’s general and specific causation opinions, as well as Dr. Brody’s partial, general causation opinions, are unreliable and unhelpful to the jury and should be excluded from evidence pursuant to Federal Rule of Evidence 702 and *Daubert*. In addition, Drs. Mark and Brody’s opinions are highly prejudicial and misleading to the jury and should be excluded under Federal Rule of Evidence 403.

This the 8th day of May, 2015.

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CERTIFICATE OF SERVICE

I hereby certify that on May 8, 2015, I electronically filed the foregoing pleading with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the following:

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